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In re Application of
Mary M. Mader et al
Serial No.: 10/535,002
Filed: May 12, 2005
Attorney Docket No.: X-16114

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: PETITION DECISION
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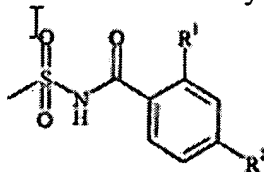
This is in response to the petition under 37 CFR 1.144, filed November 3, 2006, requesting review of the petition decision mailed October 17, 2006.

BACKGROUND

A review of the file history is set forth in the previous decision and is not repeated here. Applicants have filed this petition seeking modification of the previous petition decision based on the understanding of Lack of Unity standards set forth in the PCT Administrative guidelines and also refer to a presentation of the Technology Center made November 15, 2001.

DISCUSSION

Applicants argue that the decision does not follow PCT guidelines in determining Lack of Unity. As noted in the pervious decision, "applicants state that all of the claims are directed to compounds having as a core structure a 2,4-disubstituted benzoysulfonamide, as shown here:



As shown, this differs from Formula 1, in claim 1, only in lacking the Ar group and is found in all of the compounds, as stated by applicants." Applicants again quote the PCT guidelines for determining Unity of invention for Markush Groups, which are:

- (f)(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:
(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(ii) In paragraph (f)(i)(B)(1), above, the words **“significant structural element is shared by all of the alternatives”** refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

(iii) In paragraph (f)(i)(B)(2), above, the words “recognized class of chemical compounds” mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

(v) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

The previous decision states: “In this particular instance the benzoylsulfonamide group could be considered to constitute the significant structural element as it does occupy a large portion of the compound structure. However, this group is extremely well known and appears in many prior art references as the basis of sulfa drugs, etc., or as a significant structural element to which some type of group is attached in the Ar position. Thus it does not itself make a contribution over the prior art, but as noted above is not required to do so. Further, consideration of what Ar can be – a fused heterocyclic or non-heterocyclic structure – shows that it would be nearly as large as the benzoylsulfonamide common structure. Additionally, as applicants assert that the compounds have a common activity, it devolves that that activity must be associated with the common core or structure (see highlighted portion above), which, as has been noted above, is extremely well known and used in many different pharmaceutical applications. However, there appears to be no indication that benzoylsulfonamides possess the antitumor activity claimed herein in the prior art which leads to the presumption that the activity is provided by the Ar substituents. In view of this conclusion Lack of Unity does exist between the different Ar groups attached to the benzoylsulfonamide structure.”

Applicants’ arguments with respect to the above statement are based on the presentation, particularly slides 29 and 30 which refer to Example 18 of what was then Annex B of the Administrative Instructions for PCT. (This has been revised and is now part of Chapter 10 of the PCT Search and Examination Guidelines, however Example 18 remains the same.) It is noted that the examples set forth therein are to illustrate principles related to determination of Unity and are not to be taken literally. The example states that the indole moiety is the significant structural element shared by all alternatives. And since the same utility is alleged unity is presumed to be present. However, a caveat is given in the presentation that since the indole structure is well known and does not make a contribution over the art Lack of Unity **may** be held. The example presumes that the common utility or activity is in the core indole structure, not the variables bonded to it. Note also that the indole structure is the major portion of all of the structures represented, but is so well known that it does not form a “special technical feature” which makes a contribution over the art, even though the common property or activity is associated with it.

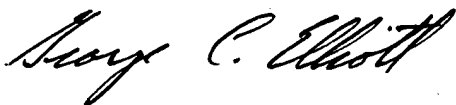
A similar situation exists here, although perhaps not clearly expressed in the previous decision. The benzoysulfonamide structure is a structure common to all members of the Markush group and possesses pharmaceutical activity (as it is the basis for many sulfa drugs). However, antitumor activity is not a known utility for benzoysulfonamides. Therefore the benzoysulfonamide structure does not provide Unity of Invention to the compounds of the Markush group because it does not possess the utility claimed. It was also noted that the Ar portion of the structure, which presumably provides the antitumor activity, is of relatively the same size, or occupies a similar large portion of the structure, but is variable and the structures encompassed by Ar do not have Unity of Invention due to their wide diversity. Here again, even if the benzoysulfonamide structure is considered to represent the major portion of the structure, it is so well known that it cannot form the special technical feature required that makes a contribution over the prior art. Alternatively, the benzoysulfonamide structure may be thought to satisfy the requirement of (b)(2) in that it forms a structure which is the basis for a recognized class of chemical compounds. However, the structure is not sufficiently large or consistently defined as to meet this criterion.

DECISION

The petition decision has been but is not modified. This petition is therefore **DENIED**.

Applicants remain under obligation to reply to the Office action of July 14, 2006, within the time period set therein, or as extended under 37 CFR 1.136(a).

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.



George C. Elliott
Director, Technology Center 1600